DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 17, 2014

Wellquest International Incorporated
% Mr. Robert Seiple, RAC
Emergo Global Consulting, LLC
816 Congress Avenue, Suite 1400
Austin, Texas 78701

Re: K132518
Trade/Device Name: NuBrilliance Pulsed Light Hair Removal System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONF
Dated: July 14, 2014
Received: July 16, 2014

Dear Mr. Seiple:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132518

Device Name
NuBrilliance Pulsed Light Hair Removal System

Indications for Use *(Describe)*

The Wellquest NuBrilliance Pulsed Light Hair Removal system device is an over-the-counter device intended for the removal of unwanted hair. The NuBrilliance Pulsed Light Hair Removal System is also intended for permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs regrowing when measured at 6, 9,a nd 12 months after the completion of the treatment regimen.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1. Submission Sponsor

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3. Date Prepared

09 August 2013

4. Device Identification

Trade/Proprietary Name: NuBrilliance Pulsed Light Hair Removal System
Common/Usual Name: Light-based hair removal device
Classification Name: Light-based, over-the-counter hair removal device
Classification Regulation: 21CFR 878.4810
Product Code: OHT
Device Class: Class II
Classification Panel: General and Plastic Surgery

5. Predicate Devices

Home Skinovations Silk'n Flash N Go Light. K103184

6. Device Description

General Information:
The NuBrilliance Pulsed Light Hair Removal System is a home-use, medical-esthetic device for long term Hair Reduction based on Intensive Pulse Light (IPL) technology. The NuBrilliance Pulsed Light Hair Removal System works below the skin's surface and therefore does not involve any cutting or pulling, reducing pain and preventing new hair growth. The NuBrilliance Pulsed Light Hair Removal System consists of the following main components: Base unit and applicator, Base-Applicator cable, and an AC cord.

The Base Unit comprises the User Interface (display/LEDs, buttons, etc.), the connection cable to the Applicator, the power cable to the grid as well as internal parts such electronics board/s and mechanical parts (fans, holders, etc.).
The Applicator is a hand held part used to remove unwanted body hair by applying the Nu Brilliance Pulsed Light Hair Removal treatment on areas such underarms, bikini line, arms and legs. It comprises a triggering button, a replaceable lamp sub-assembly, an optical safety feature as well as internal electro-mechanical parts.

The replaceable lamp cartridge is located inside the applicator inner body.
The Base Unit provides the User Interface which includes the following controls:

- Power on/off button
- Energy level selection button ("-" or "+")
- Six energy level lights - lights up green when energy level is determined
- Cartridge lamp – slowly flashes red when the cartridge requires replacement

7. Intended Use

The Wellquest NuBrilliance Pulsed Light Hair Removal System device is an over-the-counter device intended for the removal of unwanted hair. The NuBrilliance Pulsed Light Hair Removal System is also intended for permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of treatment regimen.

8. Substantial Equivalence Discussion

The following table compares the NuBrilliance Pulsed Light Hair Removal System device to the predicate device, Silk'n Flash N Go hair removal device, with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**Wellquest International, Inc.**	**Home Skinovations Ltd**	**NuBrilliance Pulsed Light Hair Removal System Comparison to Predicate**
Trade Name	NuBrilliance Pulsed Light Hair Removal System	Silk'n Flash N Go	
510(k) Number	K132518	K103184	N/A
Product Code	OHT	OHT	Identical
Regulation Number	21CFR 878.4810	21CFR 878.4810	Identical
Regulation Name	Laser surgical instrument for use in general and plastic surgery and in dermatology[1]	Laser surgical instrument for use in general and plastic surgery and in dermatology	Identical
Indications for Use	The Wellquest NuBrilliance Pulsed Light Hair Removal System device is an over-the-counter device intended for the removal of unwanted hair. The NuBrilliance Pulsed Light Hair Removal System is also intended for permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of treatment regimen.	The Silk'n Flash N Go device is an over the counter device intended for the removal of unwanted hair. Flash N Go is also intended for permanent reduction in hair regrowth defined as a long term, stable reduction in hair counts following a treatment regime.	Indications for Use for the Wellquest device changed at the request of the Agency. At the FDA's direction, the Wellquest Indications For Use are now more explicit than the predicate device
Risk Classification	II	II	Identical
Principles of operation:	LEDs produce light of specific wavelengths which acts upon the hair follicles to retard hair growth.	LEDs produce light of specific wavelengths which acts upon hair follicles to retard hair growth.	Identical
Sterile	No	No	Identical
Single-Use	No	No	Identical

[1] Product code OHT is the best fit for these devices. However please note that neither the Wellquest NuBrilliance Pulsed Light Hair Removal System device or the Skinovations Silk'n Flash N Go devices utilize laser (coherent) light. Both the subject and predicate devices utilize normal light produced by LEDs.

Manufacturer	**Wellquest International, Inc.**	**Home Skinovations Ltd**	**NuBrilliance Pulsed Light Hair Removal System Comparison to Predicate**
Trade Name	NuBrilliance Pulsed Light Hair Removal System	Silk'n Flash N Go	
Shelf Life	Yes	Yes	Identical
Battery Operated	No	No	Identical
AC Powered	Yes – 110-240VAC, 50-60 Hz	Yes – 110-240VAC, 50-60 Hz	Identical
Safety Feature: close contact detectors	Yes	Yes - optical	Identical
Safety Feature: Pigmentation Level Detector	Yes	Yes – optical – does not allow activation on dark skin	Identical
Darkest Skin allowed	Fitzpatrick 4	Fitzpatrick 4	Identical
Complies with ISO 10993 biocompatibility testing	Yes	Presumed, not mentioned in 510(k)	Assumed equivalent
Electrical Safety Testing ISO 60601 and other relevant standards	Testing passed	Presumed, not mentioned in 510(k)	Assumed equivalent
Conditions of Use	OTC product for in-home use	OTC product for in-home use	Identical
BASIC PERFORMANCE COMPARISON			
Optical aperture	7 cm^2	6 cm^2	Essentially identical. Marketing considerations lead to the selection of a larger optical aperture in order to treat a slightly larger area per pulse. Since the energy flux and the emitted spectrum are identical, this larger treatment area raises no safety concerns.

Manufacturer	**Wellquest International, Inc.**	**Home Skinovations Ltd**	**NuBrilliance Pulsed Light Hair Removal System Comparison to Predicate**
Trade Name	NuBrilliance Pulsed Light Hair Removal System	Silk'n Flash N Go	
Spectral Filter	475 nm	475 nm	Identical
Emitted Energy	5 joules/cm^2	5 joules/cm^2	Identical
User-selectable energy levels	6 levels	5 levels	Similar – no impact to safety or efficacy. Marketing considerations lead to the implementation of one more energy level for user comfort. Since the emitted energy flux and the spectrum are identical, this additional level raises no safety concerns.
Single pulse duration	4-5mSec	4-5mSec	Identical
Interval between pulses	~ 3 Sec	~ 3.5 Sec	Essentially identical. Improved electronics lead to a slightly shorter time between pulses for further user comfort. Since the energy flux and the spectrum are identical, the 0.5 sec difference in the interval between pulses raises no safety concerns.
Power Supply	110-240 VAC, 50-60 Hz	110-240 VAC, 50-60 Hz	Identical
Safety Features – - Optical Close contact detector	Yes	Yes	Identical
Pigmentation Level Detector	Optical – does not allow activation on dark skin	Optical – does not allow activation on dark skin	Identical
Darkest Skin allowed	Fitzpatrick 4	Fitzpatrick 4	Identical

9. Non-Clinical Performance Data

The following are listed as "Recognized Consensus Standards" for Product Code OHT:

- ANSI/IESNA RP27.2-2000 Recommended Practice for Photobiological Safety for Lamps and Lamp Systems – Measurement Techniques
- ANSI/IESNA RP-27.3-2007 Recommended Practice for Photobiological Safety for Lamps – Risk Group Classification and Labeling
- IEC 62471 First edition 2006-2007 Photobiological safety of lamps and lamp systems
- ANSI/IESNA RP 27.1-2005 Recommended Practice for Photobiological Safety for Lamps and Lamp Systems General Requirements

Testing performed to address the performance of the NuBrilliance Pulsed Light Hair Removal System and support substantial equivalence include:

Electrical & Electronic Safety:

- ISO 60601-1:2010, 3rd edition – Medical Electrical Equipment – Part 1: General Requirements for Safety. All requirements were met . Testing included EN 61000 – various parts: Generic Standards, emission standards for residential, commercial and light industrial environments: immunity for residential, commercial and light industrial environments, Testing and Measurement Techniques; Radiated radio frequency electromagnetic yield immunity tests, electrical fast transient burst immunity test, surge immunity tests. Voltage drops, short interruptions, voltage variations immunity tests. All requirements were met.
- ISO 60601-1-2, Edition 3, 2007. Medical Electrical Equipment - Part 1-2: General Requirements for Safety- Collateral standard: Electromagnetic Compatibility – Requirements. Al requirements were met.
- FCC title 47 and ANSI C63.4-2003. American National Standards for Methods and Measurements of Radio – Noise emissions from low voltage electrical and electronic equipment in the range from 9kHz to 4kHz. All requirements were met.
- IEC 62471 First edition 2006-2007 Photobiological safety of lamps and lamp systems All requirements were met.

Biocompatibility

- ISO 10993-1:2009 Biological evaluation of medical devices – Part 1, Evaluation and testing.
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5 – Tests for in vitro cytotoxicity.
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10 – Tests for irritation and skin sensitization.

According to ISO 10993-1:2009 with respect to the applied part for superficial (skin surface device) treatment with contact duration of less than 24h (in fact, the contact duration is of a few seconds or less for each pulse) the NuBrilliance Pulsed Light Hair Removal System should comply with Cytotoxicity, Sensitization and Irritation tests according to ISO 10993-5:2009 and ISO 10993-10:2009.

The NuBrilliance Pulsed Light Hair Removal System is a device for permanent reduction of hair growth which comes into direct body skin contact through the optical filter. The applied optical filter/colored glass has been commercially available in different IPL devices with similar properties for several years.

The current optical filter/color glass successfully passed the supplier's cytotoxicity test according to ISO 10993-5:2009 (See RD-10044 "IPL Study Protocol- Cytotoxicity Test for IPL Filter", RD-10045 "IPL Cytotoxicity Test for IPL Filter") by examining for cytotoxic effect on L-929 fibroblast cells and showed no cytotoxic effect. The Irritation test was conducted according to ISO 10933-10:2010 on New Zealand white rabbits' skin in order to assess the skin irritation. According to this test the NuBrilliance Pulsed Light Hair Removal System optical filter was classified as "non-irritant". The Sensitization test was conducted according to ISO 10993-10:2010 to evaluate the allergenic potential or sensitizing capacity of the NuBrilliance Pulsed Light Hair Removal System filter on guinea pigs. The results indicated that the test group did not show any hypersensitivity response.

Usability Testing:

Usability testing was conducted to assure that the user could follow the directions provided to safely use the device in accordance with the information provided. Twenty subjects were enrolled in the Usability Study and were provided the User Manual and instructed to read it carefully. No guidance was provided. Subjects were then introduced to task scenarios simulating the use of the device for independent treatment simulations under the investigators observation.

The results clearly indicate that the User Manual for the NuBrilliance device provides adequate guidance for independent home use hair reduction treatment and the NuBrilliance device is easy to learn and manipulate and is appropriate for home use treatment.

Summary

As part of demonstrating safety and effectiveness of the Wellquest NuBrilliance Pulsed Light Hair Removal System device and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission. Wellquest completed a number of tests test as listed above. The Wellquest NuBrilliance Pulsed Light Hair Removal System device meets all the requirements for overall design, biocompatibility, and electrical safety which confirm that the output meets the design inputs and specifications. The Device passed all testing stated above as shown by the acceptable results obtained.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device.

It has been shown in this 510(k) submission that the differences between the NuBrilliance Pulsed Light Hair Removal System and the predicate device do not raise any questions regarding its safety and effectiveness. The NuBrilliance Pulsed Light Hair Removal System device, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.